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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/537,254	06/01/2005	Richard E. Walters	05-084	1412
<div>7590 Marvin S Townsend Patent Attorney 8 Grovepoint Court Rockville, MD 20854</div>				
<div>01/06/2009</div>				
<div>EXAMINER FERNANDEZ, SUSAN EMILY</div>				
<div>ART UNIT 1651</div>				
<div>PAPER NUMBER</div>				
<div>MAIL DATE 01/06/2009</div>				
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/537,254

**Applicant(s)**

WALTERS ET AL.

**Examiner**

SUSAN E. FERNANDEZ

**Art Unit**

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 22 September 2008 and 27 February 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-6, 8, 16, 19-22, 24, 25, 28, 29, 31, 35, 38, 39 and 42-45 is/are pending in the application.
- 4a) Of the above claim(s) 24 and 25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6, 8, 16, 19-22, 28, 29, 31, 35, 38, 39 and 42-45 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

The amendments filed September 22, 2008 and February 27, 2008, have been received and entered.

Claims 7, 9-15, 17, 18, 23, 26, 27, 30, 32-34, 36, 37, 40, and 41 are cancelled. Claims 1-6, 8, 16, 19-22, 24, 25, 28, 29, 31, 35, 38, 39, and 42-45 are pending.

### ***Election/Restrictions***

In view of the amendments filed September 22, 2008, the restriction between Groups I and II is hereby withdrawn.

Applicant's election of the species polynucleotides in the reply filed on December 3, 2007 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 24 and 25 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonselected species, there being no allowable generic or linking claim.

Claims 1-6, 8, 16, 19-22, 28, 29, 31, 35, 38, 39, and 42-45 are examined on the merits to the extent they read on the elected subject matter.

### ***Specification***

The amendment filed February 27, 2008 and September 22, 2008 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added

material which is not supported by the original disclosure is as follows: (a) the recitation in page 19, lines 3-15 "between the plates having 10 million cells or more" (b) the recitation in page 27, lines 24-31 "having 10 million cells or more" (c) the recitation in page 19, lines 3-15 "per 10 milliliters".

Applicant is required to cancel the new matter in the reply to this Office Action.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-6, 8, 16, 19-22, 28, 29, 31, 35, 38, 39, and 42-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Meserol (US 5,720,921).

Meserol discloses a method and apparatus for the encapsulation of biologically-active substances in red blood cells, which can be performed in an automated, continuous-flow, self contained electroporation system (abstract). The method and apparatus can be used broadly for the incorporation of a variety of biologically-active substances in cells and lipid vesicles (column 8, lines 10-12). The apparatus is self-contained and therefore sterile (column 9, lines 22-23), thus limitations in instant claims 2 and 4 are met. Moreover, it is clear from Figure 1 that the apparatus has entry and exit ports and multiple reservoirs (thus meeting limitations in instant claims 5, 38, and 39). Note that high voltage square pulses (2.13 kV/cm, 2 ms) can be administered followed by a lower voltage exponential pulse (1.5 to 1.75 kV/cm, 5 ms) for the increased encapsulation of IHP into red blood cells (column 13, lines 23-27). Thus, limitations in instant claims 8 and 16 are met. In the method, single discrete batches can be processed (column 15, lines 5-7) and the distance between the electrodes will vary depending on the flow volume and field strength (column 15, lines 11-12). Note that parallel plate electrodes can be used, as demonstrated in Figures 9 and 10 (see column 22, lines 24-26), thus meeting limitations in instant claim 6. Moreover, limitations in instant claim 35 are taught by the reference given that gases are removed by cylinders (column 26, lines 27-29). Finally, the resulting cells can be used for therapeutic purposes (column 28, lines 8-27), thus meeting limitations in instant claims 20 and 21.

Meserol differs from the claimed invention in that it does not expressly disclose that the geometric factor of the chamber which includes the electrodes is less than or equal to  $0.1 \text{ cm}^{-1}$  or that the suspension in the apparatus has a conductivity in a range spanning 0.001 to 100 milliSiemens/cm.

Hibi et al. discloses that a method of transfecting cells with nucleic acids wherein a flow chamber is used having a volume of 50  $\mu\text{L}$  and an inter-electrode distance of 0.5 mm (column 6, lines 19-23). This results in a geometric factor less than or equal to  $0.1 \text{ cm}^{-1}$ .

At the time the invention was made, it would have been obvious to have used the geometric factor of Hibi et al. as the geometric factor of the Meserol apparatus. One of ordinary skill in the art would have been motivated to do this since there would have been a reasonable expectation of success in obtaining electroporation with such a geometric factor. Moreover, varying the volume, the electrode distance, and solution conductivity would have been a matter of routine experimentation, particularly since Meserol indicates that the distance between electrodes will vary depending on the flow volume and field strength (column 15, lines 11-12). Thus, claims 1-6, 8, 16, 19, 20, 21, 28, 29, 31, 35, 38, 39, 42, 43, 44, and 45 are rendered obvious.

Claim 22 is also rendered obvious since Hibi et al. demonstrates that a flow electroporation device is suitable for inserting nucleic acids into cells.

A holding of obviousness is clearly required.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUSAN E. FERNANDEZ whose telephone number is (571)272-3444. The examiner can normally be reached on Mon-Fri 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leon B Lankford/  
Primary Examiner, Art Unit 1651

Susan E. Fernandez  
Examiner  
Art Unit 1651

sef